IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.: _____
	)	
	)	
	)	
GALDERMA LABORATORIES INC.,	)	
GALDERMA LABORATORIES, L.P., and	)	
SUPERNUS PHARMACEUTICALS, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), for its Complaint, avers as follows:

PARTIES

1. Mylan is a corporation organized under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia.

2. Upon information and belief, defendant Galderma Laboratories, Inc. (GLI) is a corporation organized under the laws of Delaware, with a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

3. Upon information and belief, defendant Galderma Laboratories, L.P. (GLLP) is a privately held partnership registered in Texas, with a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. (GLI and GLLP are together referred to herein as "Galderma".)

4. Upon information and belief, defendant Supernus Pharmaceuticals, Inc. (Supernus) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

JURISDICTION AND VENUE

5. This action arises under the Declaratory Judgment Act, Title 28 of the United States Code, Chapter 151, for the purposes of determining an actual and justiciable controversy between the parties hereto. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over the Galderma defendants by virtue of, *inter alia*, their having conducted business in Delaware, having availed themselves of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Galderma has previously availed itself of this forum for purposes of litigating their patent disputes. For example, in the last two years, Galderma has filed at least five complaints for patent infringement in the U.S. District Court for the District of Delaware including 1:10-cv-00887-UNA; 1:10-cv-00045-LPS, 1:09-cv-00703-LPS, 1:09-cv-00483-HB, and 1:09-cv-00184-LPS.

7. This Court has personal jurisdiction over defendant Supernus by virtue of, *inter alia,* its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Supernus has previously availed itself of this forum for purposes of litigating its patent disputes. For example, in the last two years, Supernus has filed at least eight complaints for patent infringement in the U.S. District Court for the District of Delaware, *e.g.*, in 1:10-cv-00852-UNA, 1:10-cv-00851-UNA, 1:10-cv-00501-GMS, 1:10-cv-00484-SD, 1:10-cv-00397-SD, 1:10-cv-00329-SD, 1:09-cv-00882-GMS, 1:09-cv-00511-GMS.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b).

CLAIM FOR RELIEF

9. In July 2006, CollaGenex Pharmaceuticals, Inc. launched Oracea® brand doxycycline capsules (30 mg immediate release and 10 mg delayed release beads) indicated for inflammatory lesions (papules and pustules) of rosacea in adult patients pursuant to the allowance by the United States Food and Drug Administration (FDA) of New Drug Application (NDA) 50-805.

10. Upon information and belief, Galderma acquired CollaGenex for approximately $420 million in 2008. Upon information and belief, GLLP owns NDA 50-805 and is the exclusive distributor of Oracea in the United States.

11. In October 2008, Mylan submitted Abbreviated New Drug Application (ANDA) 90-855 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (FFDCA) seeking FDA approval for the commercial manufacture, use and sale of a generic version of Oracea.

12. After Mylan submitted ANDA 90-855, GLLP listed U.S. Patent Nos. 7,232,572; 7,211,267; 5,789,395; and 5,919,775 ("the Ashley and Amin patents") in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for Oracea which, upon information and belief, the FDA received on December 5, 2008.

13. After the Ashley and Amin Patents were listed in the Orange Book, Mylan amended its pending ANDA 90-855 to include a certification under § 505(j)(2)(A)(vii)(IV) of the FFDCA (Paragraph IV Certification) relating to the Ashley and Amin patents and provided Galderma notice of that certification in February 2009.

14. On March 17, 2009, the FDA denied multiple petitions that contended that the 30-month stay of the Hatch-Waxman Amendments should apply to an ANDA referencing an old

antibiotic (*e.g.*, doxycycline) if the ANDA includes a Paragraph IV Certification to a patent listed in the Orange Book by the NDA holder after the ANDA was submitted (a "later-listed patent"). With respect to Mylan's ANDA 90-855, the Ashley and Amin patents are later-listed patents.

15. On March 19, 2009, GLI and GLLP, *inter alia*, filed a complaint against Mylan in this District (09-cv-00184) alleging infringement of the Ashley and Amin patents ("the Oracea Patent Litigation"). In that complaint, GLI and GLLP asserted that they will be "irreparably harmed" by Mylan's commercial manufacture, use or sale of a generic version of Oracea.

16. On May 15, 2009, GLLP filed a petition with the FDA (Docket No. FDA-2009-P-0225). In that petition, GLLP acknowledged the FDA's March 17, 2009 ruling that the 30-month stay provisions of the Hatch-Waxman Amendments do not apply to an ANDA referencing an old antibiotic if the ANDA includes a Paragraph IV Certification to a later-listed patent. Nevertheless, GLLP's petition asked the FDA specifically to stay the approval of Mylan's ANDA 90-855 for 30 months from the date that Galderma received notification of Mylan's Paragraph IV Certification or until an earlier resolution of the Oracea Patent Litigation.

17. On November 10, 2009, the FDA denied GLLP's petition to stay the approval of Mylan's ANDA 90-855.

18. On November 23, 2009, Galderma sent an email request to the Court in the Oracea Patent Litigation asking the Court to order Mylan to provide Galderma advanced written notice of (a) Mylan's receipt of tentative and/or final approval and (b) Mylan's intent to commercially launch a generic version of Oracea. Galderma informed the Court that "Plaintiffs are concerned that Mylan may launch its generic product at risk … (as it has done before…)."

19. On December 28, 2009, the Court in the Oracea Patent Litigation denied Galderma's request.

20. At a March 23, 2010 hearing in the Oracea Patent Litigation, Galderma again asked the Court to order Mylan to provide advanced notice of Mylan's intention to launch a generic version of Oracea on the grounds that "the plaintiffs are at risk of an at-risk launch by Mylan, which would upset the apple cart in the market between now and the time this case is to be tried."

21. On April 2, 2010, Galderma filed a motion in the Oracea Patent Litigation to preliminarily enjoin Mylan from marketing a generic version of Oracea. At the May 24, 2010 hearing on Galderma's motion for preliminary injunction in the Oracea Patent Litigation, Brian Johnson testified under oath that he expects Galderma's Oracea business "will be devastated" if Mylan launches a generic version of Oracea while the Oracea Patent Litigation is pending.

22. On June 28, 2010, the Court in the Oracea Patent Litigation granted Galderma's motion for preliminary injunction.

23. On July 2, 2010, Mylan notified Galderma that Mylan had received final approval of its ANDA 90-855.

24. Trial in the Oracea Patent Litigation is scheduled for February 14-18, 2011.

25. On July 6, 2010, U.S. Patent No. 7,749,532 ("the Chang patent") entitled, "Once Daily Formulation of Tetracyclines," was issued by the United States Patent and Trademark Office to Supernus as assignee. A copy of the Chang patent is attached hereto as Exhibit A.

26. In CollaGenex's 2008 FORM 10-K filed with the U.S. Securities and Exchange Commission, Collagenex stated:

> On June 10, 2002, we executed a Development and Licensing Agreement with Supernus pursuant to which we were granted an exclusive worldwide license (including the right to

> sublicense) to use Supernus technology and patents to develop prescription products for the treatment of various inflammatory disorders. Under the agreement, certain product development functions will be performed for us by Supernus. We have committed to pay Supernus milestone payments in cash. Through December 31, 2007, the total milestone payments made to Supernus related to Oracea were $2.5 million. For rosacea-indicated development, these future payments could total up to $1.0 million in the aggregate and relate primarily to international approval and international commercialization of Oracea. Under the agreement, we must also pay Supernus royalties based on a percentage of net sales of any products utilizing any part of the licensed technology, including Oracea. We began incurring royalties to Supernus in the third quarter of 2006 as a result of our July 2006 launch of Oracea.

27. Upon information and belief, GLI is the exclusive licensee under the Chang patent.

28. Upon information and belief, shortly after the Chang patent issued, GLLP listed the Chang patent in the Orange Book. By doing so, GLLP represented that a claim of infringement of the Chang patent could reasonably be asserted against any unlicensed commercial manufacture, use and sale of a generic version of Oracea.

29. The Chang patent is invalid for failure to satisfy the requirements of Part II of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

30. The manufacture, use, offer for sale, sale, or importation of Mylan's generic version of Oracea will not directly nor indirectly infringe any valid claim of the Chang patent.

31. Galderma's conduct has created a reasonable apprehension that Galderma will file an action against Mylan alleging infringement of the Chang patent in order to prevent Mylan's commercial manufacture, use and sale of a generic version of Oracea.

32. An actual and justiciable controversy exists between the parties with respect to validity and infringement of the Chang patent.

PRAYER FOR RELIEF

WHEREFORE, Mylan prays for a judgment that:

A. Declares that the claims of the Chang patent are invalid;

B. Declares that the manufacture, use, offer for sale, sale, or importation of Mylan's generic version of Oracea will not infringe any valid claim of the Chang patent;

C. Declares that the submission of Mylan's ANDA 90-855 under § 505(j) of the FFDCA does not infringe;

D. Awards Mylan its costs and attorneys' fees; and

E. Awards Mylan such other and further relief as the Court may deem proper.

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Plaintiff
Mylan Pharmaceuticals Inc.

OF COUNSEL

Ron E. Shulman
Terry Kearney
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
Tel.: (650) 493-9300

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